EXHIBIT 19

COMPANY ANNOUNCEMENT

Torrent Pharmaceuticals Limited Issues Voluntary Nationwide Recall of Valsartan / Amlodipine / HCTZ Tablets

This recall has been completed and FDA has terminated this recall.

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

Read Announcement | View Product Photos

Summary

Company Announcement Date:

August 17, 2018

FDA Publish Date:

March 20, 2020

Product Type:

Drugs
Prescription Drugs

Reason for Announcement:

Due to The Detection of N-Nitroso N-Methyl 4-Amino Butyric Acid (NMBA)

Company Name:

Torrent Pharmaceuticals

Brand Name:

Torrent

Product Description:

Valsartan/Amlodipine/HCTZ Tablets

Company Announcement

Torrent Pharmaceuticals Limited is voluntarily recalling 14 lots of Valsartan/Amlodipine/HCTZ tablets to the consumer level due to the detection of trace amounts of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Zhejiang Huahai Pharmaceuticals. The impurity detected in the API is N-nitrosodimethylamine (NDMA), which is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification.

To date, Torrent Pharmaceuticals Limited has not received any reports of adverse events related to this recall.

Valsartan is used to control high blood pressure and for the treatment of heart failure. In combination with amlodipine plus hydrochlorothiazide, it is used to control high blood pressure. Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication. Patients who are on valsartan should continue taking their medication, as the risk of harm to the patient's health may be higher if the treatment is stopped immediately without any alternative treatment.

The products subject to recall are listed below and packaged in bottles. The product can be identified by checking the product name, manufacturer details and batch or lot number on the bottle containing these products.

NDC	Product Description	Lot/Batch	Expiration Date
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2D025	Nov-2019
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2D026	Nov-2019
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2E001	Jan-2020
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2E002	Jan-2020
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2E003	Jan-2020
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2E004	Jan-2020
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2E005	Jan-2020

NDC	Product Description	Lot/Batch	Expiration Date
NDC 13668-328-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/160mg/25mg, 30 Tablets	BBX9D004	Nov-2019
NDC 13668-328-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/160mg/25mg, 30 Tablets	BBX9E001	Jan-2020
NDC 13668-326-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 5mg/160mg/12.5mg, 30 Tablets	BBY1E001	Dec-2019
NDC 13668-326-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 5mg/160mg/12.5mg, 30 Tablets	BBY1E003	Mar-2020
NDC 13668-327-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/160mg/12.5mg, 30 Tablets	BBY2E001	Mar-2020
NDC 13668-329-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 5mg/160mg/25mg, 30 Tablets	BBY4D004	Nov-2019
NDC 13668-329-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 5mg/160mg/25mg, 30 Tablets	BBY4E001	Jan-2020

Valsartan/Amlodipine/HCTZ tablets were distributed Nationwide to Torrent's wholesale, distributor, repackager and retail customers. Torrent Pharmaceuticals Limited is notifying its distributors and customers by phone and in writing to immediately discontinue distribution of the specific lots being recalled and to notify their sub-accounts. Torrent is arranging for return of all recalled products to Qualanex. Instructions for returning recalled products are given in the recall letter.

Consumers with **medical questions regarding this recall or to report an adverse event** can contact Torrent Pharmaceuticals Limited at:

- 1-800-912-9561 (live calls received 8:00 am – 5:00 pm Eastern Time, voicemail available 24 hours/day, 7 days/week).
- Medinfo.Torrent@apcerls.com (mailto:Medinfo.Torrent@apcerls.com)

Consumers should also contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Any general **questions regarding the return of this product**please contact Qualanex at 1-800- 505-9291 (live calls received 8 am -5:30 pm Eastern Time).

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)
- Regular Mail or Fax: Download form (/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting)or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

FDA Press Announcement (/news-events/press-announcements/fda-announces-voluntary-recall-several-medicines-containing-valsartan-following-detection-impurity)

Company Contact Information

Consumers:

Torrent Medical Information

1-800-912-9561

Medinfo.Torrent@apcerls.com (mailto:Medinfo.Torrent@apcerls.com)

Product Photos


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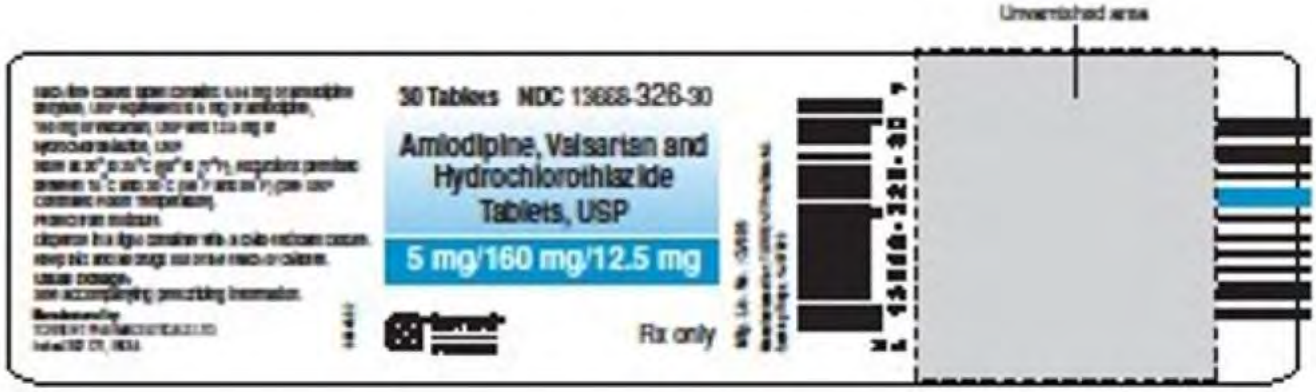
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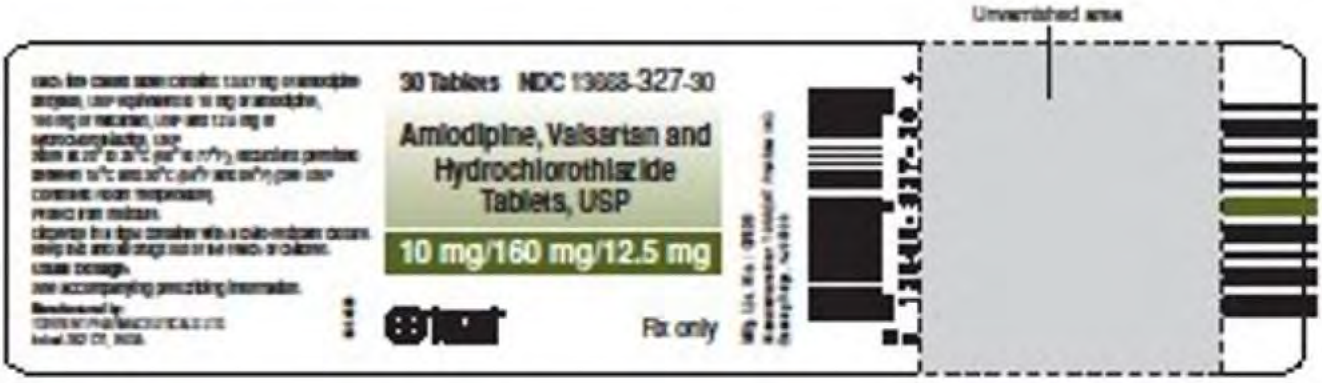
Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP
5 mg/160 mg/12.5 mg
Rx only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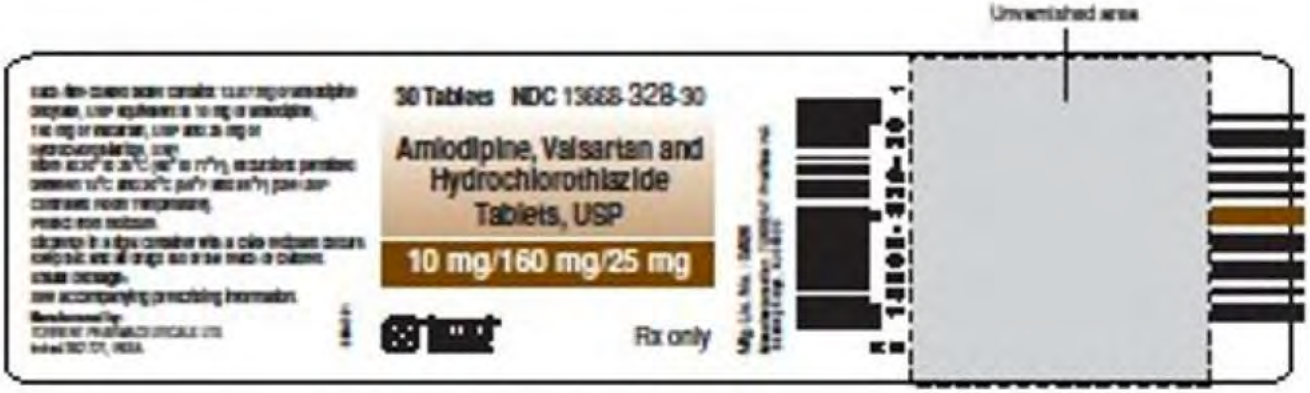
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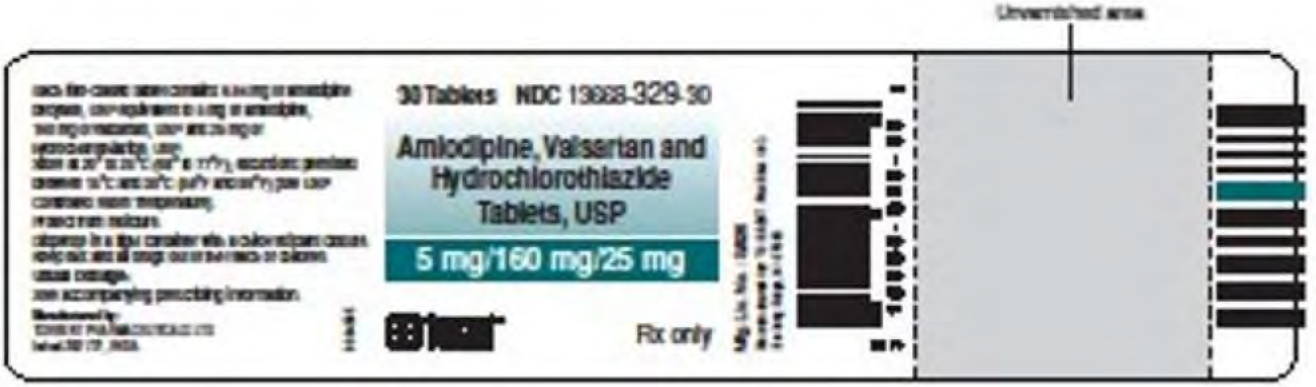
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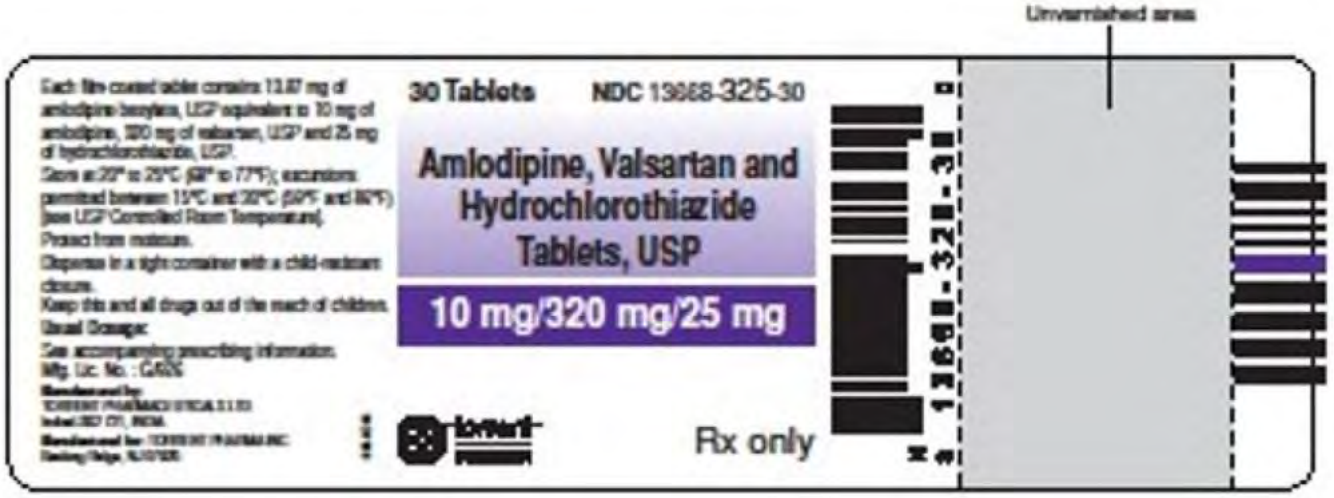

Was this helpful? Yes No

More Recalls, Market Withdrawals, & Safety Alerts (/safety/recalls-market-withdrawals-safety-alerts)